Dkt. #639-B-PCT-US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Nai-Kong CHEUNG

U.S. Serial No.:

10/621,027, continuation-in-part of International Application No. PCT/US02/01276, filed January 15, 2002, claiming benefit of U.S. Serial No.

60/261,911, filed January 16, 2001

Filed Date

July 16, 2003

For

THERAPY-ENHANCING GLUCAN

Law Offices of Albert Wai-Kit Chan, LLC

World Plaza, Suite 604 141-07 20th Avenue Whitestone, NY 11357

March 25, 2005

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir/Madam:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant hereby submits this Supplemental Information Disclosure Statement in accordance with their duty of disclosure under 37 C.F.R. §1.56. Applicant originally filed an Information Disclosure Statement for the above-identified application on July 16, 2003 and Supplemental Information Disclosure Statements on April 12, 2004, September 24, 2004, November 8, 2004 and November 22, Applicant would like to direct the Examiner's attention to the following references which are listed below as Exhibits 1-16 and on Form PTO/SB/08B (Exhibit A, 2 pages). A copy of the references cited in the International Search Report (Exhibit 1) will not be submitted because they were cited by the examiner in the December 17, 2004 non-final Office Action for the above-identified application. Further, Applicant's attorney's office may be contacted in the event that the Examiner would like a copy of all references filed with the July 16, 2003 Information Disclosure Statement, April 12, 2004 Supplemental Information Disclosure Statement, September 24, 2004,

Applicant : Nai-Kong CHEUNG

U.S. Serial No.: 10/621,027 Filed : July 16, 2003

Page : 2

November 8, 2004 and November 22, 2004 Supplemental Information Disclosure Statements.

The following references are attached:

- 1. PCT International Search Report for Sloan-Kettering Institute for Cancer Research, Int'l Application No. PCT/US04/23099, Filed July 16, 2004, Dated February 28, 2005 [Exhibit 1]
- 2. Babineau, T. et al., "Randomized Phase I/II Trial of a Macrophage-Specific Immunomodulator (PGG-Glucan) in High-Risk Surgical Patients", Annals of Surgery, Vol. 220, No. 5, Pages 601-609 (1994) [Exhibit 2]
- 3. Babineau, T. et al., "A Phase II Multicenter, Doubleblind, Randomized, Placebo-Controlled Study of Three Dosages of an Immunomodulator (PGG-Glucan) in High Risk Surgical Patients", Arch Surg, Vol. 129, Pages 1204-1210 (1994) [Exhibit 3]
- 4. Arturson, G.; Wallenius, G., "The Renal Clearance of Dextran of Different Molecular Sizes in Normal Humans", Scandinaz J Clin & Lab Investigation, Vol. 1, Pages 81-86 (1964) [Exhibit 4]
- 5. Dellinger, E., et al., "Effect of PGG-glucan on the Rate of Serious Postoperative Infection or Death Observed After High-Risk Gastrointestinal Operations", Arch Surg, Vol 134, Pages 977-983 (1999) [Exhibit 5]
- 6. Arturson, G. et al., "Intravascular Persistence and Renal Clearance of Dextran of Different Molecular Sizes in Normal Children", Arch Dis Childh., Vol. 41, Pages 168-172 (1966) [Exhibit 6]

Applicant : Nai-Kong CHEUNG U.S. Serial No.: 10/621,027

U.S. Serial No.: 10/621,027 Filed : July 16, 2003

Page: 3

7. Sortwell, R. et al., "Chronic Intravenous Administration of Lentinan to the Rhesus Monkey", Toxicology Letters, Vol. 9, Pages 81-85 (1981) [Exhibit 7]

- 8. Shimazu, H. et al., "Intravenous chronic toxicity of lentinan in rats: 6-month treatment and 3-month recovery", National Library of Medicine (PubMed), J Toxicol Sci., Pages 33-57 (1980) [Exhibit 8]
- 9. Mehvar, R., "Recent Trends in the Use of Polysaccarides for Improved Delivery of Therapeutic Agents: Pharmacokientic and Pharmacodynamic Perspectives", Current Pharmaceutical Biotechnology, Vol. 4, Pages 283-302 (2003) [Exhibit 9]
- 10. Hanaue, H. et al., "Basic Studies on Oral Administration
 of Lentinan (I)", J. Jpn. Soc. Cancer Ther., Vol. 8,
 Pages 1566-1571 (1989) [Exhibit 10]
- 11. Kidd, P., "The Use of Mushroom Glucans and Proteoglycans
 in Cancer Treatment", Alternative Medicine Review, Vol.
 5, No. 1, Pages 4-27 (2000) [Exhibit 11]
- 12. Hanaue, H. et al, "Effects of Oral Lentinan on T-Cell Subsets in Periphel Venous Blood", Clinical Therapeutics, Vol. 5 (1989) [Exhibit 12]
- 13. Suzuki, M. et al, "Antitumor and Immunological Activity of Lentinan in Comparison with LPS", International Society for Pharmacology, Pages 463-468 (1994) [Exhibit 13]
- 14. Cheung, N.; Modak, S.; "Oral $(1\rightarrow 3)$, $(1\rightarrow 4)$ - β -D-Glucan Synergizes with Antiganglioside GD2 Monoclonal Antibody

Applicant

Nai-Kong CHEUNG

U.S. Serial No.: Filed :

10/621,027 July 16, 2003

Page

4

3F8 in the Therapy of Neuroblastoma", Clinical Cancer Research, Vol. 8, Pages 1217-1223 (2002) [Exhibit 14]

- 15. Chihara, G. et al., "Antitumor and Metastasis-Inhibitory Activities of Lentinan as an Immunomodulator: An Overview", Cancer Detection and Prevention Supplement Vol. 1, Pages 423-443 (1987) [Exhibit 15]
- 16. Mayer, L.; Shao, L., "Therapeutic Potential of Oral Tolerance", Nature Reviews Immunology, Vol. 4, Pages 407-419 (2004) [Exhibit 16]

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

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Respectfully submitted,

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Albert Wai-Kit Chan Registration No. 36,479 Attorney for Applicant Law Offices of Albert Wai-Kit Chan, LLC World Plaza, Suite 604 141-07 20th Avenue Whitestone, New York 11357 Tel: (718) 357-8836

Fax: (718) 357-8836

E-mail: kitchanlaw@aol.com

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

1

Sheet

Complete if Known			
Application Number	10/621,027		
Filing Date	July 16, 2003		
First Named Inventor	Nai-Kong Cheung		
Art Unit	1623		
Examiner Name	Jason H. Johnsen		
Attorney Docket Number	639-B-PCT-US		

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	T .
Initials*	No. ¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	PCT International Search Report for Sloan-Kettering Institute for Cancer Research, Int'l Application No. PCT/US04/23099, Filed July 16, 2004, Dated February 28, 2005	
	2	Babineau, T. et al., "Randomized Phase I/II Trial of a Macrophage-Specific Immunomodulator (PGG-Glucan) in High-Risk Surgical Patients", Annals of Surgery, Vol. 220, No. 5, Pages 601-609 (1994)	
	3	Babineau, T. et al., "A Phase II Multicenter, Double-blind, Randomized, Placebo-Controlled Study of Three Dosages of an Immunomodulator (PGG-Glucan) in High Risk Surgical Patients", Arch Surg, Vol. 129, Pages 1204-1210 (1994)	
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	5	Dellinger, E., et al., "Effect of PGG-glucan on the Rate of Serious Postoperative Infection or Death Observed After High-Risk Gastrointestinal Operations", Arch Surg, Vol 134, Pages 977-983 (1999)	
	6	Arturson, G. et al., "Intravascular Persistence and Renal Clearance of Dextran of Different Molecular Sizes in Normal Children", Arch Dis Childh., Vol. 41, Pages 168-172 (1966)	
	7	Sortwell, R. et al., "Chronic Intravenous Administration of Lentinan to the Rhesus Monkey", Toxicology Letters, Vol. 9, Pages 81-85 (1981)	·
	8	Shimazu, H. et al., "Intravenous chronic toxicity of lentinan in rats: 6-month treatment and 3-month recovery", National Library of Medicine (PubMed), J Toxicol Sci, Pages 33-57 (1980)	
	9	Mehvar, R., "Recent Trends in the Use of Polysaccarides for Improved Delivery of Therapeutic Agents: Pharmacokientic and Pharmacodynamic Perspectives", Current Pharmaceutical Biotechnology, Vol. 4, Pages 283-302 (2003)	
	10	Hanaue, H. et al., "Basic Studies on Oral Administration of Lentinan (I)", J. Jpn. Cancer Ther., Vol. 8, Pages 1566-1571 (1989)	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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Substitute for form 1449/PTO		Complete if Known			
			•	Application Number	10/621,027
INFORMATION DISCLOSURE			CLOSURE	Filing Date	July 16, 2003
STATEMENT BY APPLICANT		First Named Inventor	Nai-Kong Cheung		
(Use as many sheets as necessary)			ecassan)	Art Unit	1623
(and an inary directs as necessary)		Examiner Name	Jason H. Johnson		
Sheet	2	of	2	Attorney Docket Number	639-B-PCT-US

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²			
	11	Kidd, P., "The Use of Mushroom Glucans and Proteopglycans in Cancer Treatment", Alternative Medicine Review, Vol. 5, No. 1, Pages 4-27 (2000)			
	12	Hanaue, H. et al, "Effects of Oral Lentinan on T-Cell Subsets in Periphel Venous Blood", Clinical Therapuetics, Vol. 5 (1989)			
	13	Suzuki, M. et al, "Antitumor and Immunological Activity of Lentinan in Comparison with LPS", International Society of Pharmacology, Ltd., Pages 463-468 (1994)			
	Cheung, N.; Modak, S.; "Oral (1•3), (1•4)-B-D-Glucan Synergizes with Antiganglioside GD2 Monoclonal Antibody 3F8 in the Therapy of Neuroblastoma", Clinical Cancer Research, Vol. 8, Pages 1217-1223 (2002)				
	15	Chihara, G. et al., "Antitumor and Metastasis-Inhibitory Activities of Lentinan as an Immunomodulator: An Overview", Cancer Detection and Prevention Supplement, Vol. 1, Pages 423-443 (1987)			
	16	Mayer, L.; Shao, L., "Therapeutic Potential of Oral Tolerance", Nature Reviews Immunology, Vol. 4, Pages 407-419 (2004)			

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